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10/594,037	09/25/2006	Hirobumi Aoki	Q80830	8966
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/594,037

**Applicant(s)**

AOKI ET AL.

**Examiner**

ABIGAIL FISHER

**Art Unit**

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

Receipt of Amendments/Remarks filed on March 23 2009 is acknowledged.

Claims 1, 4-5 and 7-11 were amended. Claims 1-15 are pending.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 1-15 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is **withdrawn** in light of Applicants' amendments filed on March 23 2009 deleting the term derivative.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 1-15 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is **withdrawn** in light of Applicants' amendments and

arguments filed on March 23 2009 in which the terms "an inositol combined with a saccharide" was amended to "a compound produced by reacting an inositol with a saccharide" and explaining what is meant by the term "constitutional unit".

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 1-3, 5-6, 9-10, 12-13 and 15 under 35 U.S.C. 102(b) as being anticipated by Jain (US PG PUB No. 2003/0068297) is **withdrawn** by Applicants' amendments filed on March 23 2009 in which the terms "an inositol combined with a saccharide" was amended to "a compound produced by reacting an inositol with a saccharide".

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 4, 7-8, 11 and 14 under 35 U.S.C. 103(a) as being unpatentable over Jain in view of Minami et al. (JP-10-114614, cited on PTO Form 1449) is **withdrawn** by Applicants' amendments filed on March 23 2009 in which the terms "an inositol combined with a saccharide" was amended to "a compound produced by reacting an inositol with a saccharide".

#### **Maintained Rejections**

**Claims 1-3, 5 and 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sleevi et al. (US Patent No. 6492339).**

#### **Applicant Claims**

Applicants claim an external preparation for skin comprising a compound produced by reacting an inositol with a saccharide. A specific saccharide claimed is glucose. The claimed amount of the inositol is from 0.01 to 50% by mass of the preparation. Additionally claimed is a cosmetic comprising the external preparation above.

#### **Determination of the Scope and Content of the Prior Art (MPEP §2141.01)**

Sleevi et al. is directed to compositions comprising D-chiro inositol. It is taught that the term D-chiro-inositol includes the inositol, derivatives thereof, or compounds containing D-chiro inositol. Examples include polysaccharides containing D-chiro-inositol and one or more additional sugars such as glucose, galactose, and mannose (column 4, lines 20-45). Formulations of the invention are suitable for administration in oral, nasal, topical, rectal, vaginal and or parenteral form (column 8, lines 29-32). Dosage forms for topical or transdermal administration include powders, sprays, ointments, pastes, creams, lotions, gels, solutions, patches and inhalants (columns 9-10, lines 66-67 and 1-5). The active ingredients can be incorporated in amount from 0.01 to 99.5% (column 10, lines 47-52).

#### **Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)**

Sleevi et al. do not exemplify a topical formulation comprising polysaccharides containing D-chiro-inositol. However, Sleevi et al. do teach that topical is one suitable dosage form that the polysaccharides containing D-chiro-inositol are one suitable form of the inositol.

***Finding of Prima Facie Obviousness Rationale and Motivation  
(MPEP §2142-2143)***

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to utilize polysaccharides containing D-chiro-inositol such as polysaccharides containing D-chiro-inositol and glucose. One of ordinary skill in the art would have been motivated to utilize polysaccharides containing D-chiro-inositol and glucose as Sleevi et al. teach that suitable compounds containing D-chiro-inositol include polysaccharides. It would have been obvious to one of ordinary skill in the art to try the different D-chiro-inositol compounds taught by Sleevi et al. as a person with ordinary skill has good reason to pursue known options within his or her technical grasp.

**Note: MPEP 2141 [R-6] *KSR International CO. v. Teleflex Inc.* 82 USPQ 2d 1385 (Supreme Court 2007).**

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to utilize polysaccharides containing D-chiro-inositol such as polysaccharides containing D-chiro-inositol and glucose in a topical formulation. One of ordinary skill in the art would have been motivated to formulate a topical dosage formulation as Sleevi et al. specifically teach that this is one suitable formulation for the delivery of D-chiro-inositol containing compounds. It would have been obvious to one of

ordinary skill in the art to formulate D-chiro-inositol into different dosage forms depending on the desired end use.

Regarding the claimed amount of inositol derivative, Sleevi et al. teach an amount that overlaps that instantly claimed. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. **See MPEP 2144.05 [R-5]**

### ***Response to Arguments***

Applicants argue that Sleevi et al. discloses a composition containing the mixture of inositol and additional sugars but the instant claims recite an external preparation comprising a compound produced from the reaction of an inositol with a saccharide.

Applicants' arguments filed March 23 2009 have been fully considered but they are not persuasive.

As written Sleevi et al. states that the "a compound containing D-chiro-inositol" is any compound that contains the D-chiro-inositol moiety as part of a larger structural composition. Illustrative examples of these compound include polysaccharides containing D-chiro-inositol and one or more additional sugars such as glucose, galactose and mannose. Therefore, Sleevi et al. teaches compositions comprising an inositol as part of a larger polysaccharide comprising other sugars such as glucose. This larger structural composition is therefore a compound that is made from both an inositol and a saccharide.

Therefore, the rejection is maintained since applicant has not provided any persuasive arguments to overcome the rejection.

**Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lamothe et al. (US Patent No. 5518733) in view of Satou (JP Patent No. 63196596, English Translation submitted).**

#### **Applicant Claims**

Applicants claim an external preparation for skin comprising an inositol derivative in which an inositol is combined with a saccharide. A specific saccharide claimed is glucose. A specific the inositol claimed is myo-inositol. The claimed amount of the inositol and saccharide is from 0.01 to 50% by mass of the preparation. Additionally claimed is a cosmetic comprising the external preparation above.

#### **Determination of the Scope and Content of the Prior Art (MPEP §2141.01)**

Lamothe et al. is directed to cosmetic compositions containing oligosaccharides. Lamothe et al. teach cosmetics which create a medium favorable for the development of beneficial endogenous flora. It was found that oligosaccharides of the invention were metabolized in the presence of certain strains such as Lactobacillus pentosus, which produces lactic acid, and acidified culture medium. However, pathogenic strains such as staphylococcus aureus do not metabolize or very slightly metabolize the oligosaccharides (column 1, lines 17-36). The oligosaccharides taught include gluco-oligosaccharides, fructo-oligosaccharides and galacto-oligosaccharides (column 1, lines 43-47). The amount of oligosaccharide present in the cosmetic is from 0.1 to 20%

(column 2, lines 63-65). Exemplified are various different cosmetic formulations (soap, shampoo, face cream and vaginal gel) comprising the oligosaccharides.

**Ascertainment of the Difference Between Scope the Prior Art and the Claims  
(MPEP §2141.012)**

Lamothe et al. do not teach that the oligosaccharide comprises myo-inositol. However, this deficiency is cured by Satou et al.

Satou et al. is directed to the formation of gluco-oligosaccharides and attaching an inositol residue in the end. The gluco-oligosaccharide has the general formula of  $(\text{Glc})_n-(\text{Glc})-\text{Ino}$  wherein Glc represents glucose and Ino represent inositol (claim 1). The inositol as claimed is myo-inositol. It is general taught that oligosaccharides are known in the art as biochemical reagents for amylase activity measurements, low-dental caries inducing sweeteners, and growth-promoting substances for bifidobacterium (page 3, related art). The oligosaccharides of Satou et al. comprising inositol are useful as growth-promoting substances for Bifidobacterium (pages 4-5 and 19, objective of the invention and Table 1).

**Finding of Prima Facie Obviousness Rationale and Motivation  
(MPEP §2142-2143)**

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Lamothe et al. and Satou et al. and utilize gluco-oligosaccharides comprising inositol in the cosmetic of Lamothe et al. One of ordinary skill in the art would have been motivated to utilize these gluco-oligosaccharides because Lamothe et al. teach the formation of cosmetic compositions

comprising gluco-oligosaccharides that create a medium favorable for the development of beneficial endogenous flora such as by generating lactic acid and Satou et al. teach gluco-oligosaccharides that promote the growth of a lactic acid generating bifidobacterium. Since both Lamothe et al. and Satou et al. teach oligosaccharides that promote the growth of beneficial endogenous flora one of ordinary skill in the art would have a reasonable expectation of success of utilizing the gluco-oligosaccharides of Satou et al. in the cosmetic formulation of Lamothe et al.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

### ***Response to Arguments***

Applicants argue that (1) the technical field of Lamothe et al is quite different from that of Satou et al. Lamothe et al. is directed to cosmetic compositions that promote the development of bacterium strains that constitute a major portion of the skin or vaginal flora whereas Satou is directed to Bifidobacterium which is a major bacterial that makes up the gut flora. Therefore, applicants argue that one of ordinary skill would not have a reason to use the gluco-oligosaccharides having an inositol of Satou et al. in the composition of Lamothe et al. because the bacterium benefited is different. Therefore, applicants argue that there is no reasonable expectation of success. Applicants argue that (2) Satou et al. discloses that the inositol-oligosaccharides are consumed in the

colon so as to promote the growth of Bifidobacterium and that this raises the possibility of consumption of these inositol-oligosaccharides by other strains of bacteria including non-beneficial strains.

Applicants' arguments filed March 23 2009 have been fully considered but they are not persuasive.

Regarding applicants' first argument, Lamothe et al. is directed to the utilizing of oligosaccharides that crease a medium favorable for the development of beneficial endogenous flora such that the flora participates in maintaining the good physicochemical balance of the skin and mucous membranes. One particular bacteria is Lactobacilli which produces lactic acid. Specific oligosaccharides taught are gluco-oligosaccharides. Satou et al. is directed to gluco-oligosaccharides which have an inositol residue attached at the end. Therefore, the oligosaccharides taught by Satou et al. fall within the class of oligosaccharides taught by Lamothe et al. in that both are directed to gluco-oligosaccharides. As evidenced by Carella et al. (WO 97/29763), both lactobacillus and bifidobacterium are lactic acid bacteria (page 1, lines 21-22). It is taught here that growth factors for facilitating the growth of lactic acid bacteria include oligosaccharides (page 2, lines 24-26). It is taught that lactobacillus inhabit the urogenital and gastrointestinal tracts of animals and humans (page 6, lines 26-35) and also inhabiting the urogenital and gastrointestinal tracts of mammals are species of the genus of Bifidobacterium (page 7, lines 18-25). Therefore, since Lamothe et al. teach administration of gluco-oligosaccharides for the generation of beneficial flora of the skin and mucous membranes (specifically vaginal) and since Carella et al. indicates that

Bifidobacterium is found both in the urogenital and gastrointestinal tracts, one of ordinary skill in the art would have a reasonable expectation that utilizing gluco-oligosaccharides of Satou et al. would be beneficial for the generation of the bifidobacterium found in the urogenital area (i.e. for vaginal applications). Therefore, applicants' arguments that there is no reasonable expectation of success are not found persuasive.

Regarding applicants' second argument, as indicated above Carella et al. indicates that bifidobacterium are found in both the gastrointestinal tracts and urogenital areas of mammals. Lamothe et al. recognizes that there may be some metabolism of oligosaccharides by pathogenic or opportunistic strains, however gluco-oligosaccharides are known to be utilized for the production of beneficial strains such as lactobacillus and bifidobacterium. Therefore, although there is the possibility that they may be consumed by non-beneficial strains, the teachings of Lamothe et al. recognizes this but it does not appear (based on the teachings of Lamothe et al.) to be a reason not to utilize the oligosaccharides in order to enhance the production of beneficial strains of flora.

Therefore, the rejection is maintained since applicant has not provided any persuasive arguments to overcome the rejection.

### ***Conclusion***

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABIGAIL FISHER whose telephone number is (571)270-3502. The examiner can normally be reached on M-Th 9am-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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